UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, August 30, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 9480-4/ Sani-Cloth
DP Barcode: D340887

To: Velma Noble, PM 31/ Drusilla Copeland
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
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Through: Karen Hicks, Team Leader
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Applicant: PDI

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
n-Alkyl dimethyl thylbenzyl ammonium chlorides	0.25
n-Alkyl dimethyl benzyl ammonium chlorides	0.25
Isopropyl alcohol	55.00
Other Ingredient(s):	44.50
Total:	100.00

1) BACKGROUND: PDI, Inc., has submitted a primary eye and a primary skin irritation study to support a change in the signal word of their product, "Sani-Cloth Germicidal Wipes".

This submission has an issue in that the registration product is Sani-Cloth Germicidal Wipes; but, the test material is Improved Germicidal Cleaning Solution. This issue is clarified on the last page of MRID Number 471229-03:

"I confirm that this study was conducted on the EPA registered product 'Sani-Cloth Germicidal Wipes', EPA Reg. No. 9480-4"

The Chemistry and Toxicology Team (CTT) was not able to locate prior acute toxicity reviews of this product. The registrant's consultant states that 9480-4 is an old registration, and, that acute toxicity reviews for this product cannot be located.

2) RECOMMENDATIONS: PSB findings are:

a) The primary eye and skin irritation studies are acceptable.

b) As no prior acute toxicity reviews of this product can be located, this product will have an incomplete acute toxicity profile.

The acute toxicity profile for Registration Number 9480-4 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity		?	Data Gap
Acute Dermal Toxicity		?	Data Gap
Acute Inhalation Toxicity		?	Data Gap
Primary Eye Irritation	471229-04	I	Acceptable
Primary Skin Irritation	471229-03	III	Acceptable
Dermal Sensitization		?	Data Gap

3) LABELING:

a) The signal word is "DANGER", based upon the results of the primary eye irritation study.

b) Due to the data gaps, CTT cannot provide complete Precautionary Statements for this product. However, the Precautionary Statements should *include* the following statements:

"Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse."

c) Due to the data gaps, CTT cannot provide complete First Aid statements. However, the First Aid statements should *at least* include the following:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing.
- Call a Poison Control Center for treatment advice.

If on Skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center for treatment advice.

d) This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards).

e) Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP **in addition to** Restricted-Use Classification. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 471229-04 **Study Completion Date**: 3/13/2007
Lab Project ID: 07-019-1

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author(s): Michael Kukulinski

Quality Assurance (40 CFR §160.12): Included

Test Material: Improved Germicidal Cleaning Solution (Sani-Cloth Germicidal Wipes)
Dosage: 0.1 mL

Species: New Zealand White rabbit **Sex**: Males
Weight: 2.42 - -2.53 kg **Age**: 8-10 weeks
Source: Kuiper Rabbitry

Summary:

1. **Toxicity Category**: I

2. **Classification**: Acceptable

Procedure (Deviations From §81-4): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	---	3/3	3/3	3/3	---	3/3	3/3	3/3
Iritis	3/3	3/3	3/3	3/3	---	0/3	0/3	0/3
Conjunctivae								
Redness	3/3	3/3	3/3	3/3	---	3/3	0/3	0/3
Chemosis	3/3	3/3	2/3	1/3	---	0/3	0/3	0/3
Discharge	3/3	3/3	3/3	3/3	---	2/3	0/3	0/3

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 471229-03 **Study Completion Date**: 3/6/2007
Lab Project ID: 07-019-2

Testing Laboratory: Tox Monitor Laboratories, Inc.
Study Director: Michael Kukulinski

Quality Assurance (40 CFR §160.12): Included

Test Material: Improved Germicidal Cleaning Solution (Sani-Cloth Germicidal Wipes)
Dosage: 0.5 mL

Species: New Zealand White rabbit
Weight: 2.58 – 2.67 kg **Age**: 8-10 weeks
Source: Kuiper Rabbitry

Summary:

1. **Toxicity Category**: III

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): None

Results: Very slight erythema was observed in 3/3, very slight edema in 2/3 and slight edema in 1/3 test material-treated animals ½-hour after exposure. Twenty-four, forty-eight and seventy two hours after exposure, well-defined erythema was observed in 1/3 and very slight erythema was observed in 2/3 test material-treated animals. Seven days after exposure, 3/3 test material-treated animals displayed very slight erythema.